DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

September 4, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Kevin L. Cornwell
President and CEO
Utah Medical Products, Inc.
7043 South 300 West
Midvale, Utah 84047

Ref. #: DEN-01-47

Dear Mr. Cornwell:

On June 4 through 8, 2001 Investigator Thai T. Duong of our office conducted an inspection of Utah Medical Products, Inc., in Midvale, Utah. Our investigator determined that your firm manufactures various products, including the INTRAN PLUS IUPC, intrauterine pressure monitoring catheters, the DELTRAN-PLUS line of disposable pressure transducer and blood sampling systems for critical care monitoring, the Finesse line of electrosurgical generators and various other products used in labor and delivery/obstetrics, neonatal intensive care, gynecology/urology/electrosurgery and blood pressure monitoring . These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820. The deviations are as follows:

1. Inadequate corrective and preventative action (CAPA) procedures, as evidenced by:

   - Not analyzing all significant sources of quality data, and using appropriate statistical methodology where necessary to detect recurring quality problems, as required by 21 CFR 820.100(a)(1). For example, your firm has failed to identify all potential sources of quality data such as in-process rejects, Medical Device

- Reporting (MDRs), maintenance records or quality audits. These are not captured, trended or evaluated.

- There is no evidence that changes in methods or procedures identified to correct and prevent the recurrence of quality problems have been made, as required by 21 CFR 820.100(a)(5). For example, "incorrect dimension" was noted as a prominent problem on your Incoming Inspection Rejection trending report for the year 2000, however, there is no indication that any corrective action was taken to address the identified issues and to prevent the recurrence of this problem.

Your response of June 27, 2001, is inadequate because although your response states that you will maintain MRB meeting minutes that will document corrective and preventive actions taken for the problems identified in the trending reports, your procedure does not address the timeframes required in which to close out corrective actions, nor does it discuss how your firm will prioritize outstanding corrective and preventive actions to ensure that significant issues are handled expeditiously.

2. Inadequate Device History Records (DHRs) in that acceptance records do not demonstrate that devices are manufactured in accordance with the Device Master Record (DMR), as required by 21 CFR 820.184(d). For example, DHRs permit the [redacted] of [redacted] whereas the DMR requires [redacted] for the acceptance of the INTRAN PLUS and IUP-300.

Your response of June 27, 2001, is inadequate. Your response states that the original Device Master Record (DMR-004), originally released March 1996, contained the correct [redacted], and that the version of the DMR reviewed by our investigator contained a typographical error. By your response, you state that this typographical error has existed since July 1997. This error therefore went undiscovered for over four years since the document was revised and was not disclosed by your firm through either audits or management review. Your response mentions that this was also an issue raised in our August 15, 1995 Warning Letter. We noted that in your August 4, 1995 response to the FDA 483 issued on July 27, 1995, and in your August 31, 1995 response to Compliance Officer Shelly Maifarth of our office, you committed to new procedures that would require reference and compliance with the device master records. For example, your August 4, 1995 reply states, "...I have authorized a new QA position targeting closer monitoring of product compliance throughout manufacturing operations in accordance with Device Master Records." Your August 31, 1995 correspondence addressed to Ms. Maifarth stated that, "The current combination of properly written device master records and a new internal audit procedure...that requires reference and compliance with the device master records will provide the right mechanism for QA identification, and subsequent corrective actions." Despite these promised corrections, our inspection revealed your firm continues to have the same problems.

Your June 27 correspondence also states that after consultation with FDA's Office of Device Evaluation in 1995, your firm decided that the change in [redacted] did not require a new 510(k) for this device. Our understanding of the significance of the

[redacted] is that it represents how far the indicated pressure reading is from the actual pressure reading. You have still failed to submit documentation showing that broadening this specification has no adverse effects on the device. Your July 31, 1995 memo to the file only states that, "...over the length of IUP-400's market history, Utah Medical has received very few complaints related to the unbalance or sensitivity of the sensor." This statement is not a substitute for proper documentation and the information you have attached to document your rationale not to submit a new 510(k) is insufficient to prove that this change in specifications is insignificant.

3. Failure to document acceptance activities to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(e). For example, your firm has failed to document the results of testing required to be performed, such as Testing Tubing for Leaks ([redacted]); Thread Wires Through Housing and Tubing ([redacted]); INTRAN PLUS Switch Plus ([redacted]); Overmold Primer Application INTRAN PLUS/INTRAN III ([redacted]) and Overmolding Process INTRAN PLUS/INTRAN III ([redacted]).

   Your June 27, 2001, response is inadequate. You state that Form 7469 was an internal document used only to communicate between work shifts. 21 CFR 820.80 requires device manufacturers to document ALL acceptance activities to demonstrate that each lot meets specific criteria. This means that documentation must include any and all data generated, such as number of units tested, test results and product scrapped. Your response indicates that you will sign off on the applicable lines of the Work Order for those operations which cannot be visually confirmed. This response does not satisfy the requirement to document the results of these operations.

4. Failure to validate processes with a high degree of assurance where the results cannot be fully verified by subsequent inspection and testing, and have those processes approved and documented according to established procedures, as required by 21 CFR 820.75(a). For example, your firm has not validated the [redacted] for the INTRAN PLUS Products. Evaluation of complaints from January 2000 to April 2001 indicates a large number involved problems with the adhesive application.

   Your June 27, 2001, response indicating that this process will be validated by August 2001 appears adequate.

5. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). For example, your procedures are inadequate in that there is no documentation of the determination of the need for an investigation or of the notification of the persons or organizations responsible for the nonconformance. There is no requirement to document the evaluation and any investigation of non-conforming products.

   Also, your firm has failed to establish procedures for rework to include re-testing and reevaluation after rework, to ensure that the product meets its current approved specifications, as required by 21 CFR 820.90(b)(2). For example, there is no evidence that

rework performed according to the Non-Conforming Materials Procedure (✗✗✗✗ ') have been evaluated for potential adverse effects on the quality of the finished product, i.e. NCMR # ✗✗ , #✗✗ and #✗✗ . According to this procedure, "rework" and "use as is" dispositions require sufficient documentation on or attached to the NCMR providing an assessment of the potential adverse effects (or lack thereof) of the rework or use on the quality of the finished product.

Your June 27, 2001, response regarding your Non-Conforming Materials procedure, ✗✗ ✗ ✗ is inadequate. You state that you have amended this procedure to clarify the use of the check-off box on the NCMR form to indicate a need for investigation. Review of section 4.11 of your Non-Conforming Materials procedure states, "Consider whether further investigation or corrective/preventive action is required to address the cause of the problem and prevent its recurrence. If no action is required, check the 'no' space on the NCMR form. If action is required, generate a corrective/preventive action per '✗✗ ✗✗✗ ..." Although this may document the need for a corrective/preventive action, this doesn't describe how or if an investigation will be documented. It is important to document all the steps taken in any investigation and the resulting conclusions, as well as the corrective/preventive actions.

Regarding your response to the lack of documentation regarding re-worked product, we agree that retraining appears to be required in order to ensure that your staff is following all procedures. However, as mentioned under item #2 above, your management reviews and internal audits have failed to disclose these deviations. 21 CFR 820.20(c) requires review of the suitability and effectiveness of the quality system by management, to be conducted at sufficient frequency to ensure that the requirements of the quality systems regulations are met. 21 CFR 820.22 requires the conducting of quality audits to assure that the quality system is in compliance with established quality system requirements and to determine the effectiveness of the quality system. The failure of your firm to determine these deficiencies is an indication that your management reviews and your quality audits are not adequate or effective.

6. Statistical techniques are inadequate in that sampling plans are not based on valid, statistical rationales, as required by 21 CFR 820.250(b). For example, your incoming inspection sampling and in-process testing procedures require the same number of units to be inspected regardless of the lot size. Also, there is no requirement to tighten the sampling size in response to findings of repeated non-conforming material.

   Your June 27, 2001, response states that you rely upon ✗✗✗✗ ✗✗✗✗ quality system to assure that the break-away introducers meet its (✗✗ specifications and that you do not have your own independent specifications for the introducer. Because of this you indicate that you are deleting the requirement for incoming inspection of these components and will replace it with the following statement, "Incoming components should be visually inspected for contamination and/or damage and identified as the component specified on the purchase order." It is your responsibility to establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. While you are required to assess the capability of suppliers, contractors and consultants to provide quality products and services (21 CFR 820.50), inspections and tests

and other verification tools are also an important part of ensuring that components and finished devices conform to approved specifications. The statement, "Incoming components should be visually inspected for contamination and/or damage....", does not define what is meant by contamination or damage, nor does it describe acceptance and rejection criteria or how to document the findings of this inspection.

With regards to your responses concerning the use of electronic records and signatures, we find your reply adequate. 21 CFR 11.100 requires that prior to or at the time of use, firms must certify to the Agency that the electronic signatures in their system, used on or after August 20, 1997, are intend to be the legally binding equivalent of traditional handwritten signatures. Also, 21 CFR 11.10 requires these systems to be validated and to employ procedures and controls designed to ensure the authenticity, integrity, and when appropriate, the confidentiality of electronic records. This part also requires that adequate controls exist to ensure the distribution of, access to and use of documentation for system operation and maintenance. Your system must also guarantee that only authorized individuals can access the system. Please be aware of these requirements if you decide in the future to institute the use of electronic signatures/records.

Again we wish to reiterate that deficiencies similar to those found in the current inspection, were found during the inspection conducted in July 1995. In correspondence signed by you in response to that inspection, you committed to institute changes that would correct these deviations. Our observations during this inspection indicate that you have not made such corrections. A quality system that has been implemented effectively and is monitored to identify and address problems is more likely to produce devices that function as intended.

The above identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment is in compliance with all requirements of the Federal regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the QS/GMP deficiencies are reasonably related will be cleared until the violations are corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

In order to facilitate FDA in making the determination that such corrections have been made, thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, to resume marketing clearance for Class III devices for which a 510(k) premarket notification or Premarket Approval application (PMA) have been submitted, and provide Certificates to Foreign Governments for products manufactured at your facility, we are requesting that you submit certification by an outside consultant to this office on the schedule below. Certification by an outside expert consultant should contain assurance that he/she has

conducted an audit of your establishment's manufacturing and quality assurance systems relative to the requirements of the device QS/GMP regulation (21 CFR, Part 820). You should also submit a copy of the consultant's report with certification that you have reviewed the report and that your establishment has initiated or completed all corrections called for in the report.

The initial certifications of audit and corrections, and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates:

- Initial certifications by consultant and establishment – November 30, 2001.
- Subsequent certifications – bi-monthly thereafter until all corrections have been made.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by us without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of any other additional steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Regina A. Barrell, Compliance Officer, Food and Drug Administration, Denver District, P. O. Box 25087, Denver, CO 80225-0087. If you have any further questions, please feel free to contact Ms. Barrell at (303) 236-3043.

Sincerely,

Thomas A. Allison, Acting for

Thomas A. Allison
District Director